



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License for: Convection Enhanced Delivery of a
Therapeutic Agent with a Surrogate Tracer for Treating Cancer and Urological Diseases

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404.7, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the inventions embodied in: HHS Ref. No E-202-2002/0 “Method for Convection Enhanced Delivery of Therapeutic Agents”, U.S. Provisional Patent Application 60/413,673 (filed September 24, 2002; expired), International Patent Application No. PCT/US2003/30155 (filed September 24, 2003; nationalized), U.S. Patent Application 7,371,225, European Patent Application 03756863.1, Australian Patent 2003299140, to Medicenna Therapeutics, Inc. having a principle place of business in 1075 West Georgia St, Vancouver, BC, Canada V6E 3C9.

The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be in a field of use directed to the treatment of cancers and urological disorders that express IL-4 receptor on their cell surface by administering cpIL4-PE38KDEL by convection enhanced delivery along with a Gd-DTPA surrogate tracer.

DATE: Only written comments and/or applications for a license that are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael Shmilovich, Esq, CLP, Senior Licensing and Patent Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; E-mail: shmilovm@mail.nih.gov. A signed confidential disclosure agreement may be required to receive copies of the patent application assuming it has not already been published under either the publication rules of either the U.S. Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION:

The invention is a method for monitoring the spatial distribution of therapeutic substances by MRI or CT that have been administered to tissue using convection enhanced delivery, a technique that is the subject of now expired NIH-owned U.S. Patent

No. 5,720,720 (HHS Ref. E-173-1992/0). The tracer is a molecule, detectable by MRI or CT, which functions as a surrogate for the motion of the therapeutic agent through the solid tissue. In other particular embodiments, the tracer is the therapeutic agent conjugated to an imaging moiety. The method of this invention uses non-toxic macromolecular MRI contrast agents such as chelated Gd(III). These macromolecular imaging agents have clearance properties that mimic the pharmacokinetic properties of co-administrated drugs, so as to be useful in quantifying the range and dosage level of therapeutic drugs using MR imaging.

The prospective exclusive license will be royalty-bearing and comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 30 days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

December 17, 2013
Date

Richard U. Rodriguez,
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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